

November 24, 2002

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Office of Public Wealth, Science, FDA, HHS
Dockets Management Branch (HFA-305)
Docket Number 02N- 0466
Food and Drug Administration
5630 Fishers Lane
Room 1061, Rockville, M.D 20852

RE: Solicitation of Public Review
And Comment of Research Protocol: A
Multicenter, Randomized of Dryvax
Administered to Children 2 to 5 Years
Of Age

Docket Number 02N-0466

TO WHOM THIS MAY CONCERN:

As an American citizen I am extremely concerned about the small pox vaccination that could possibly be tested on forty children between the ages of two through five. Based on the information I have gathered the forty children that will be given the weakened dose of the small pox vaccine will be placed in a great deal of danger. These children will not receive any medical benefit from this vaccination, unless there is a bio terrorist attack on America. Small pox was eradicated in 1972, and at this point in time there is no need for this vaccination, especially when the lives of small children will be placed in danger.

One of the difficulties that will be faced during the trial run of this vaccination is the confinement of the forty children. Children at these ages need to develop mentally, socially, and physically. That will be difficult for those forty children to do when they are going to need to spend one month in confinement. Another situation that may cause a problem is the care that these forty children will need during that month of confinement. The parents of these children may not be able to stay at home and care for them. If that is the case the children will need to be kept at some type of institution, away from their families. That will be difficult for both the children and their parents.

One of the bigger concerns is that these children may be able to infect others with small pox. They are going to be injected with a live virus that could cause many side effects. If the child touches their eyes they could go blind. Even though the injection site will be covered with some type of bandage it does not guarantee that the child will not be able to get it off. If the child passes the small pox on to others the results could be devastating. A study done in the 1960's showed that fifteen out of every one million

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people vaccinated will suffer life-threatening reactions, especially those with weak immune system. Mainly those infected with HIV or AIDs. The vaccine will also cause one of two of those fifteen to die, an estimated 280 million Americans.

There is another issue at hand. Where will these forty children be coming from? Will there be a money incentive offered to the families that volunteer their children? That will most likely be the case. That will mean that there will be more people of poor and minority backgrounds interested in participating in the study. A study that will set a standard for all of American's children will need a great deal of diversity. Judging by the circumstances that will prove to be an extremely difficult task.

If the study is conducted the Bush Administration will offer the small pox vaccination to every American who wants it. At the moment most Americans will not be ready to get a vaccination that could possibly have deadly side effects, unless it is absolutely necessary. Most of America will not be convinced that they will need the small pox vaccination simply based on a study conducted on forty children.

In conclusion, I am strongly against administering the small pox vaccination to forty children. The side effects and risks involves are far to dangerous for those forty children to face. The vaccine will have no medical benefit to the children, therefore these children should not be vaccinated.

Sincerely,
Stephanie Salazar